MAR 2 9 2006

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K053521

1. **Submitter's Identification:**
   Mr. Guixi Liu
   Shijiazhuang Hongxiang Plastic Products Co., Ltd.
   New High Technologies Industrial Zone
   Luquan City, Hebei, China

   Date Summary Prepared: November 30, 2005

2. **Name of the Device:**
   Shijiazhuang Hongxiang Plastic Products Co., Ltd.
   Pre-Powdered Sterile Vinyl Glove, Clear

3. **Predicate Device Information:**
   Shijiazhuang Great Eagle Plastic Prodcuts Co., Ltd.
   Synthetic Powdered Vinyl Patient Examination Gloves K#983645

4. **Device Description:**
   Classified by FDA's General and Plastic Surgery Device panel as Class I, 21 CFR 880.6250, Powdered vinyl Patient Examination Glove, 80LYZ, Powdered with Absorbable Dusting Powder, USP, and meets all requirements of ASTM Standard D5250-00 $^{\varepsilon 4}$.

5. **Intended Use:**
   A patient examination glove is a disposable device intended for medical purposes that is worn on the hand of healthcare and similar personnel to prevent contamination between healthcare personnel and the patient's body, fluids, waste or environment.

6. **Comparison to Predicate Devices:**

Shijiazhuang Hongxiang Plastic Products Co., Ltd.'s Pre-Powdered Sterile Vinyl Glove, Clear is substantially equivalent in safety and effectiveness to the Shijiazhuang Great Eagle Plastic Products Co., Ltd.'s Synthetic Powdered Vinyl Patient Examination Gloves.

7. **Discussion of Non-Clinical tests performed for Determination of Substantial Equivalence are as follows:**

The standards used for Shijiazhuang Hongxiang Plastic Products Co., Ltd glove production are based on ASTM D-5250-00 [4]. All testing meets requirements for Physical and Dimensions Testing conducted on gloves, Inspection Level S-2, AQL4.0.

The FDA 1000 ml. Water Fill Test based on ASTM D 5151-99 was also conducted with samplings of AQL 2.5, Inspection Level I, meeting these requirements. Primary Skin irritation and Skin Sensitization (allergic contact dermatitis) testing was conducted with results showing no primary skin irritant or sensitization reactions.

There are no special labeling claims and we do not claim our gloves as hypoallergenic on our labels. However, the following statement will appear on our labeling: "Caution: Users should consider the circumstances of use in deciding whether to remove residual powder from gloves after donning. Powder can be removed by wiping gloves thoroughly with a sterile wet sponge, sterile wet towel, or other effective methods."

A powder limit test that based on ASTM D-6124-01 for starch at finished inspection is conducted insure that our gloves meet our "powdered" claim (contain no more than 10 mg/dm^2).

8. **Discussion of Clinical Tests Performed:**

Not Applicable- There is no hypoallergenic Claim.

9. **Conclusions:**

Shijiazhuang Hongxiang Plastic Products Co., Ltd., Pre-Powdered Sterile Vinyl Glove, Clear, conforms fully to ASTM D-5250-00[4] standard as well as applicable 21 CFR references, and meets pinhole FDA requirements, biocompatibility requirements and labeling claims as shown by data in Section 7. There are no safety/efficacy issues or new claims from the "substantial equivalence" products cited.

UPDATE TO 510(k) SUMMARY

SHIJIAZHUANG HONGXIANG PLASTIC PRODUCTS CO., LTD.

New High Technologies Industrial Zone, Luquan City, Hebei, China

Name and address of the Radiation Sterilization Agency:

Radiation Health Research Institute of Hebei Province

No. 428, Heping West Rd., Shijiazhuang City, Hebei Province 050071, China

Tel: 86-311-87045091

According to the original bioburden, our sterilization dose was determined as per method indicated in ANSI/ISO 11137 standard. With 25 KGY sterilization dose, which is the international custom.

We state hereby that this Pre-powdered Sterile Vinyl Glove, Clear are steriled as per ANSI/ ISO 11137, the sterilization process is validated, and the sterilization results conform to the specification of SAL 10^{-6}. We conformance to the cited sterile packaging requirements.

The sterilization process:

1. Determine sterilization dose
2. Put potassium dichromate dosimeter at the areas where the products are radiated at maximum and minimum position, to determine the absorbed dose of the products.
3. Stick microorganism indicator on the radiated products, and the indicator spores of Bacillus pumilus.
4. Put the products on the special transmitting equipment, and mark the transmitting vehicle to go into the radiation sterilization room. It runs continuously as per the determined dose and time.
5. Inspect the products after radiation sterilization.

Packaging Description:

The packaging used is paper bags and heat-sealable pouches which are able to bear radiation sterilization. Their seal strength is good and conforms to the packaging for terminally sterilized medical devices requirement. They can maintain the sterility of the products with respect to its intended use, transport and storage condition.

We hereby state that the integrity and seal of the packaging used for Pre-Powdered, Sterile, Vinyl, Clear Examination Gloves conform to BS EN 868 sterile packaging requirements.

21. **Glove Biocompatibility:**

The following skin irritation and dermal sensitization studies were carried out to determine the biocompatibility status of the glove:

Test	Result
(a) Primary Skin Irritation Test (Modified Draize Test)	The test material was not irritating to the skin of the rabbits. (see Exhibit #4)
(b) Dermal Sensitization Study (Buehler Method)	An extract of this test material did not appear to produce any skin irritation on the guinea pigs. (see Exhibit #4)

In summary, the biocompatibility tests carried out on this glove showed no indication of a potential cause for skin irritation or sensitization.

22. **Color or Flavor Additives:**

There are no color and flavor additives used.

23. **Shelf Life/ Expiration Date:**

We are not claiming any shelf life/ expiration dates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2006

Shijiazhuang Hongxiang Plastics Products Company, Limited
C/O Mr. William Wang
Gloveco, Incorporated
3973 Schaefer Ave.
Chino, California 91710

Re: K053521
Trade/Device Name: Pre-powdered sterile vinyl examination glove, clear
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: Class I
Product Code: LYZ
Dated: February 15, 2006
Received: March 14, 2006

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment A

Page 1 of 1

510(k) NUMBER (IF KNOWN): K053521

DEVICE NAME: **Shijiazhuang Hongxiang Plastic Products Co., Ltd.**

INDICATIONS OFR USE: **Pre-Powdered Sterile Vinyl Examination Glove, Clear**

INDICATIONS FOR USE:

A patient examination glove is disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use _____ (Per 21 CFR 801.109)

OR

Over-The-Counter-Use V (Optional Formal 1-2-96)

(PLEASE DO NOT WIRTE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrent of CDRH, Office of Device Evaluation (ODE)

3/24/06

General Hospital

Devices

K053521